



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

URTHALER *et al.*

Appl. No.: 10/806,346

Filed: March 23, 2004

For: **Methods and Devices For  
Producing Biomolecules**

Confirmation No.: 3985

Art Unit: 1636

Examiner: McGillem, Laura L.

Atty. Docket: 0652.2620001/EKS/AES

**Information Disclosure Statement Under 37 C.F.R. § 1.97(c)**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **FP1** to **FP21** and **NPL1** to **NPL23** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, **US1** to **US4**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

In accordance with 37 C.F.R. § C.F.R. 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **FP2**, **FP5**, **FP11**, **FP12**, **FP14**, and **FP20** cited on Form  
03/30/2007 MBELETE1 00000027 10006346  
PTO/SB/08A: 02 FC:1006 100.00 0P

Document **FP2**, WO 93/11218 A1, is in the German language. An English language abstract of document **FP2** is attached as document **NPL19**.

Document **FP5**, WO 96/08500 A1, is in the German language. An English language abstract of document FP5 is attached as document **NPL20**.

Document **FP11**, WO 98/11208 A1, is in the French language. An English language abstract of document FP11 is attached as Document **NPL21**.

Document **FP12**, EP 0 875 271 A2, is in the German language. An English language abstract of document FP12 is attached as document **NPL19**.

Document **FP14**, WO 99/37750 A1, is in the French language. An English language abstract of document FP14 is attached as document **NPL22**.

Document **FP20**, WO 02/057446 A1, is in the German language. An English language abstract of document FP20 is attached as document **NPL23**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.




Ann E. Summerfield  
Attorney for Applicants  
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Date: March 29, 2007

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Atty. Dkt. No. 0652.2620001/EKS/AES

 <p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.</p> <p>Substantive Patent No. 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p><i>(Use as many sheets as necessary)</i></p>					<b>Complete if Known</b>	
					Application Number	10/806,346
					Filing Date	March 23, 2004
					First Named Inventor	Jochen URTHALER
					Art Unit	1636
					Examiner Name	McGillem, Laura L.
Sheet 1 of 3					Attorney Docket Number	0652.2620001/EKS/AES

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>4</sup> (if known)				
	FP1	EP 0 376 080 A1	07/04/1990	Talent SRL		
		WO 93/11218 A1	06/10/1993	Diagen Institut Für Molekularbiologische Diagnostik GmbH		Abs
	FP2					
	FP3	WO 95/21250 A2	08/10/1995	Vical Incorporated		
	FP4	WO 96/02658 A1	02/01/1996	Merck & Co., Inc.		
	FP5	WO 96/08500 A1	03/21/1996	Qiagen GmbH		Abs
	FP6	WO 96/21729 A1	07/18/1996	Vical Incorporated		
	FP7	WO 96/36706 A1	11/21/1996	Merck & Co., Inc.		
	FP8	WO 97/23601 A1	07/03/1997	Genzyme Corporation		
	FP9	WO 97/29190 A1	08/14/1997	Therexsys Limited		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Examiner Signature		Date Considered	
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TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  
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Substitute for form 1449A/PTO

**Complete if Known**

Application Number	10/806,346
Filing Date	March 23, 2004
First Named Inventor	Jochen URTHALER
Art Unit	1636
Examiner Name	McGille, Laura L.
Attorney Docket Number	0652.2620001/EKS/AES

Sheet	3	of	3
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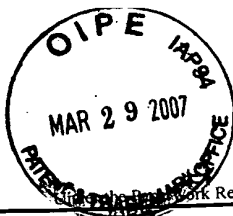
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PTO/SB/08B (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/806,346
Filing Date	March 23, 2004
First Named Inventor	Jochen URTHALER
Art Unit	1636
Examiner Name	McGillem, Laura L.
Attorney Docket Number	0652.2620001/EKS/AES

Sheet 1 of 3

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	ASENJO, J.A., and ANDREWS, B.A., "Enzymatic Cell Lysis for Product Release," in <i>Separation Processes in Biotechnology</i> , Asenjo, J.A., ed., Marcel Dekker, Inc., New York, NY, pp. 143-175 (1990)	
	NPL2	BIRNBOIM, H.C., and DOLY, J., "A rapid alkaline extraction procedure for screening recombinant plasmid DNA," <i>Nucleic Acids Res.</i> 7:1513-1523, Information Retrieval Limited (1979)	
	NPL3	CARLSON, A., <i>et al.</i> , "Mechanical Disruption of <i>Escherichia coli</i> for Plasmid Recovery," <i>Biotechnol. Bioeng.</i> 48:303-315, John Wiley & Sons, Inc. (1995)	
	NPL4	CICCOLINI, L.A.S., <i>et al.</i> , "Time Course of SDS-Alkaline Lysis of Recombinant Bacterial Cells for Plasmid Release," <i>Biotechnol. Bioeng.</i> 60:768-770, John Wiley & Sons, Inc. (1998)	
	NPL5	CICCOLINI, L.A.S., <i>et al.</i> , "A Mass Balance Study to Assess the Extent of Contaminant Removal Achieved in the Operations for the Primary Recovery of Plasmid DNA from <i>Escherichia coli</i> Cells," <i>Biotechnol. Bioeng.</i> 77:796-805, John Wiley Sons, Inc. (March 2002)	
	NPL6	CHASE, H.A., "Purification of proteins by adsorption chromatography in expanded beds," <i>Trends Biotechnol.</i> 12:296-303, Elsevier Science Ltd. (1994)	
	NPL7	DIOGO, M.M., <i>et al.</i> , "Separation and Analysis of Plasmid Denatured Forms Using Hydrophobic Interaction Chromatography," <i>Anal. Biochem.</i> 275:122-124, Academic Press (1999)	
	NPL8	FERREIRA, G.N.M., <i>et al.</i> , "Development of Process Flow Sheets for the Purification of Supercoiled Plasmids for Gene Therapy Applications," <i>Biotechnol. Prog.</i> 15:725-731, American Chemical Society and American Institute of Chemical Engineers (1999)	
	NPL9	FERREIRA, G.N.M., <i>et al.</i> , "Anion exchange purification of plasmid DNA using expanded bed adsorption," <i>Bioseparation</i> 9:1-6, Kluwer Academic Publishers (2000)	
	NPL10	FOSTER, D., "Cell Disruption: Breaking Up is Hard to Do," <i>Biotechnology</i> 10:1539-1541, Nature Publishing Co. (1992)	

Examiner  
SignatureDate  
Considered

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		Attorney Docket Number	0652.2620001/EKS/AES
Sheet	2	of	3

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL11	LEVY, M.S., <i>et al.</i> , "Effect of shear on plasmid DNA in solution," <i>Bioprocess Eng.</i> 20:7-13, Springer-Verlag (1999)	
	NPL12	LEVY, M.S., <i>et al.</i> , "The effects of material properties and fluid flow intensity on plasmid DNA recovery during cell lysis," <i>Chem. Eng. Sci.</i> 54:3171-3178, Elsevier Science Ltd. (1999)	
	NPL13	MARQUET, M., <i>et al.</i> , "Process Development for the Manufacture of Plasmid DNA Vectors for Use in Gene Therapy," <i>BioPharm.</i> 20:26-37, UCB-Bioproducts S.A. (1995)	
	NPL14	PRAZERES, D.M.F., <i>et al.</i> , "Large-scale production of pharmaceutical-grade plasmid DNA for gene therapy: problems and bottlenecks," <i>Trends Biotechnol.</i> 17:169-174, Elsevier Science (1999)	
	NPL15	RUSH, M.G., and WARNER, R.C., "Alkali Denaturation of Covalently Closed Circular Duplex Deoxyribonucleic Acid," <i>J. Biol. Chem.</i> 245:2704-2708, The American Society of Biological Chemists, Inc. (1970)	
	NPL16	THEODOSSIOU, I., <i>et al.</i> , "The processing of a plasmid-based gene from <i>E. Coli</i> . Primary recovery by filtration," <i>Bioprocess Eng.</i> 16:175-183, Springer-Verlag (1997)	
	NPL17	THEODOSSIOU, I., <i>et al.</i> , "Methods of enhancing the recovery of plasmid genes from neutralised cell lysate," <i>Bioprocess Eng.</i> 20:147-156, Springer-Verlag (1999)	
	NPL18	VARLEY, D.L., <i>et al.</i> , "Production of plasmid DNA for human gene therapy using modified alkaline cell lysis and expanded bed anion exchange chromatography," <i>Bioseparation</i> 8:209-217, Kluwer Academic Publishers (1999)	
	NPL19	Dialog File 351, Derwent World Patents Index, Accession No. 6383967, English language abstract for WO 93/11218 A1 and EP 0 875 271 A2 (Documents FP2 and FP12 on accompanying PTO/SB/08A)	
	NPL20	Dialog File 351, Derwent World Patents Index, Accession No. 7564643, English language abstract for WO 96/08500 A1 (Document FP5 on accompanying PTO/SB/08A)	

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/806,346
				Filing Date	March 23, 2004
				First Named Inventor	Jochen URTHALER
				Art Unit	1636
				Examiner Name	McGillem, Laura L.
				Attorney Docket Number	0652.2620001/EKS/AES
Sheet	3	of	3		

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Examiner Signature		<input type="checkbox"/> Citation is in conformance with MPEP 609. Draw line through citation if not in conformance and	

Examiner Signature	Considered
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